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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,348	07/20/2005	Sitke Aygen	P70555US0	1732

136 7590 01/12/2010

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EXAMINER	
NATNITHITHADHA, NAVIN	

ART UNIT	PAPER NUMBER
3735	

MAIL DATE	DELIVERY MODE
01/12/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,348	AYGEN, SITKE	
	Examiner	Art Unit	
	NAVIN NATNITHITHADHA	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. According to the Amendment, filed 09 September 2009, the status of the claims is as follows:

Claims 3-5 are new; and

Claims 1 and 2 are cancelled.

2. The objections to claims 1 and 2 (now new claims 3 and 4) are WITHDRAWN in view of the Amendment, filed 09 September 2009.

Response to Arguments

3. Applicant's arguments, see Remarks, pp. 4-5, filed 09 September 2009, with respect to the rejection of claims 1 and 2 (now new claims 3 and 4) under 35 U.S.C. 1112, first paragraph, as failing to comply with the enablement requirement, have been fully considered, and are persuasive. Therefore, the rejection of claims 1 and 2 are withdrawn.

4. Applicant's arguments, see Remarks, p. 6, filed 09 September 2009, with respect to the rejection of claims 1 and 2 (now new claims 3 and 4) under 35 U.S.C. 101 as being directed to non-statutory subject matter, have been fully considered, and are not persuasive.

Applicant's arguments, see Remarks, p. 6, are not persuasive in view of *In re Bilski* , 545 F.3d 943, 88 USPQ2d 1385 (Fed. Circ. 2008). See 35 U.S.C. 101 rejection below.

5. Applicant's arguments, see Remarks, pp. 6-8, filed 09 September 2009, with respect to the rejection of claim 1 (now new claim 3) under 35 U.S.C. 102(e) as being Ben-Oren et al, U.S. Patent No. 7,338,444 B2 ("Ben-Oren"), have been fully considered, and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made below.

6. Applicant's arguments, see Remarks, pp. 7-8, filed 09 September 2009, with respect to the rejection of claim 2 (now new claim 4) under 35 U.S.C. 102(e) as being unpatentable over Ben-Oren, as applied to claim 1 (now new claim 3), and further in view of Ghoos, GB 2360845 A ("Ghoos"), have been fully considered, and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made below.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 3-5 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim(s) 3-5 are rejected under 35 U.S.C. 101 as being directed to non-statutory subject matter because these claims are method or process claims that do not transform underlying subject matter (such as an article or materials) to a different state or thing, nor are they tied to a particular machine. *See Diamond v. Diehr*, 450 U.S. 175, 184 (1981) (quoting *Benson*, 409 U.S. at 70); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978) (citing *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876)). *See also In re Bilski* , 545 F.3d 943, 88 USPQ2d 1385 (Fed. Circ. 2008), where the Fed. Cir. held that method claims must pass the "machine-or-transformation test" in order to be eligible for patent protection under 35 USC 101. Claims 3-5 do not past the "machine-or-transformation test" because they are not tied to a particular machine or apparatus (no machine or apparatus is recited) or does not particularly transform a particular article to a different state or thing (no transformation of a particular article is recited).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Oren et al, U.S. Patent No. 7,338,444 B2 ("Ben-Oren"), in view of Katzman et al, U.S. Patent No. 6,186,958 B1 ("Katzman").

Claim 3: Ben-Oren teaches the following:

A method for determining gastric emptying (see Abstract) comprising determining $^{13}CO_2$ content in exhaled respiratory air of a patient (see col. 3, l. 57, to col. 4, l. 51, and col. 19, ll. 61-67), followed by

orally administering to the patient free ^{13}CO-octanoic acid together with a standardized test meal, wherein the free ^{13}C-octanoic acid is in a form bound to egg yolk (see col. 3, l. 57, to col. 4, l. 51, and col. 19, ll. 61-67), followed by

determining $^{13}CO_2$ content in exhaled respiratory air of the patient (see col. 3, l. 57, to col. 4, l. 51, and col. 19, ll. 61-67).

Ben-Oren does not teach "wherein body-related conversion factors are dispensed with". However, Katzman teaches a breath analyzer for use with a method for determining gastric emptying (see col. 6, l. 52, to col. 7, l. 4), which determines $^{13}CO_2$ content in exhaled respiratory air of the patient (see col. 12, ll. 25-63, and col. 13, ll. 18-45). As Applicant has argued in the Remarks, p. 4, filed 09 September 2009, "...'how' the presently claimed method 'dispenses with body related conversion factors' is simply by not using them." Based on this reasoning, Katzman teaches the limitation "body-related conversion factors are dispensed with" by not using them, since Katzman does not disclose using body-related conversion factors. It would have been obvious for one of ordinary skill in the art to modify Ben-Oren's determining $^{13}CO_2$ content in exhaled respiratory air of the patient in order to provide the following advantage, as suggested by Katzman, see col. 6, l. 52, to col. 7, l. 17:

> The present invention seeks to provide an improved breath test analyzer which overcomes disadvantages and drawbacks of existing analyzers, which provides accurate results on-site in times of the order of minutes, and which is capable of implementation as a low cost, low volume and weight, portable instrument. The breath analyzer of the present invention is sufficiently sensitive to enable it to continuously collect and analyze multiple samples of the patient's breath from the beginning of the test, and process the outputs in real time, such that a definitive result is obtained within a short period of time, such as of the order of a few minutes.

> Such a breath test analyzer is suitable for the detection of various disorders or infections of the gastro-intestinal tract, or metabolic or organ malfunctions, and since it can provide results in real time without the need to send the sample away to a special testing center or central laboratory, can be used to provide diagnostic information to the patient in the context of a single visit to a physician's office, or at any other point of care in a health care facility.
>
> In accordance with a preferred embodiment of the present invention, there is provided a breath test analyzer, including a very sensitive gas analyzer, capable of measuring the ratio of two chemically identical gases but with different molecular weights, resulting from the replacement of at least one of the atoms of the gas with the same atom but of different isotopic value. Since the isotopically labeled gas to be measured in the patient's breath may be present only in very tiny quantities, and since, in general, it has an infra-red absorption spectrum very close to that of the non-isotopically labeled gas, the gas analyzer must be capable of very high selectivity and sensitivity, to detect and measure down to the order of a few parts per million of the host gas.

9. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Oren in view of Katzman, as applied to claim 1 above, and further in view of Ghoos, GB 2360845 A ("Ghoos").

Claims 4 and 5: Ben-Oren teaches all the limitations of claim 1 as discussed above. Ben-Oren does not teach "the test meal comprises a fried egg, into which fried egg the free ^{13}CO-octanoic acid is stirred, a slice of toasting bread, 5 to 10 g of margarine or butter, and 150 ml of water or coffee", and "^{13}CO-octanoic acid is administered in an amount of about 40 mg to 100 mg".

However, Ghoos teaches the following:

a method for determining the gastric emptying (see Abstract), characterized in that the test meal comprises a fried egg, into which fried egg the free ^{13}CO-octanoic acid is stirred, a slice of toasting bread, 5 to 10 g of margarine or butter, and 150 ml of

water or coffee (see p. 6), and characterized in that ^{13}CO-octanoic acid is administered in an amount of about 40 mg to 100 mg (see p. 5).

It would have been obvious for one of ordinary skill in the art to modify Ben-Oren's test meal to have the test meal taught by Ghoos because Ghoos' test meal, which considered a standardized test meal in the prior art, is within the scope of Ben-Oren's parameters for a test meal (see Ben-Oren, col. 4, ll. 20-44).

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to NAVIN NATNITHITHADHA whose telephone number is (571)272-4732. The examiner can normally be reached on Monday-Friday, 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Navin Natnithithadha/
Examiner, Art Unit 3735
12/31/2009